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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,263	07/12/2001	Mary Ellen Rybak	OC01000KQ	3021

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER
HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
1642	5

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,263	RYBAK ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-17, in Paper No. 4, filed Nov. 6, 2002, is acknowledged.

Claims 1-20 are pending.

Claims 18-20, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1-17 are examined on the merits.

Information Disclosure Statement

2. References AW and BQ were not considered because they were not found in the parent file 09/545,312. Also, the listing of reference AW lacks a statement of the source or journal title and a publication date.

Claim Rejections - 35 USC § 112

3. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is indefinite because it is not clear how it further limits claim 1, from which it depends. Claim 1 is drawn to a method of treating a patient having melanoma which has been surgically removed comprising administering pegylated interferon alpha; and claim 8 is drawn to a method of claim 1, where the pegylated interferon alpha is administered after surgical excision of the primary melanoma.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-9, 11, 12, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirkwood et al (Kirkwood, J.M. et al., J. Clinical Oncol. 14(1): 7-17, 1996; cited in the IDS) in view of Gilbert et al (U.S. 5,951,974; issued Sep. 14, 1999; filed Dec. 19, 1997; cited in

the IDS), in view of Glue et al (U.S. 5,908,621; issued June 1, 1999; filed Apr. 29, 1997; cited in the IDS), and further in view of Talpaz et al (Blood, 92(10): 1998, page 251a; cited in the IDS).

Claims 1-9, 11, 12, and 14-27 are drawn to methods of treating patients having melanoma with pegylated interferon alpha, or interferon alpha-2b. For claims 1-9, 11, 12 and 14 the patient has a surgincally removed melanoma. For claims 15-17 the patient has a cutaneous melanoma.

Kirkwood teaches a method of treating treatment naive patients with resected cutaneous melanoma using interferon alpha-2b, and teaches that interferon alpha-2b treatment results in increased median relapse-free survival time and increased overall median survival time (page 10, 1st column). Kirkwood fails to teach methods of treating with pegylated interferon alpha, fails to teach treatment of treatment-experienced patients or patients intolerant to interferon alpha or resistant to interferon alpha. Kirkwood fails to teach the dosages and treatment schedules as claimed. Gilbert teaches pegylation of interferon alpha-2b for the purpose of increasing circulating life, solubility and decreasing antigenicity (see column 1, lines 16-23). Glue teaches a method of using pegylated interferon alpha to treat viral infection and teaches that using pegylated interferon alpha over unconjugated interferon alpha decreases side effects normally associated with administration of interferon alpha (column 3, lines 6-11). Talpaz teaches the use of pegylated interferon alpha-2b for the treatment of chronic myelogenous leukemia, and reports improved pharmacokinetics. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have substituted pegylated interferon alpha-2b for the unconjugated interferon alpha-2b of Kirkwood, because of the art-recognized benefits of pegylation as taught by Gilbert and Glue and demonstrated by Talpaz. It would have been obvious to use the methods of Kirkwood with pegylated interferon alpha for the treatment of treatment-experienced, treatment-intolerant or treatment-resistant patients, because pegylation of interferon alpha reduces side-effects and would allow the administration of higher doses of interferon alpha.

The dosages and treatment schedules recited in the claims are within the skill of one of ordinary skill in the art and it would have been obvious to optimize the dose schedules and dose levels to determine optimal schedules and dosages.

9. Claims 1-8, 10, 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Creagan et al (Creagan et al., J. Clinical Oncol. 13(11): 2776-2783, 1995) in view of Gilbert et al (U.S. 5,951,974; issued Sep. 14, 1999; filed Dec. 19, 1997), and further in view of Glue et al (U.S. 5,908,621; issued June 1, 1999; filed Apr. 29, 1997).

Claims 1-8, 10, 11, 13, and 14 are drawn to methods of treating patients with a surgically removed melanoma comprising administering pegylated interferon alpha or interferon alpha-2a.

Creagan teaches a method of treating treatment-naive patients and treatment-experienced patients with resected malignant melanoma using interferon alpha-2a, and teaches that, for stage II patients, interferon alpha-2a treatment results in a possible benefit for stage II patients (page 2781, 2nd column). Creagan fails to teach methods of treating with pegylated interferon alpha, fails to teach methods of treating patients intolerant to interferon alpha or resistant to interferon alpha. Creagan fails to teach the dosages and treatment schedules as claimed. Gilbert teaches pegylation of interferon alpha-2b that may be used for the pegylation of interferon alpha-2a (column 4, lines 15-30). Pegylation increases circulating life, solubility and decreasing antigenicity (see column 1, lines 16-23). Glue teaches a method of using pegylated interferon alpha to treat viral infection and teaches that using pegylated interferon alpha over unconjugated interferon alpha decreases side effects normally associated with administration of interferon alpha (column 3, lines 6-11). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have substituted pegylated interferon alpha-2a for the unconjugated interferon alpha-2a of Creagan because of the art-recognized benefits of pegylation as taught by Gilbert and Glue. It would have been obvious to use the methods of

Creagan with pegylated interferon alpha for the treatment of treatment-intolerant or treatment-resistant patients because pegylation of interferon alpha reduces side-effects and would allow the administration of higher doses of interferon alpha.

The dosages and treatment schedules recited in the claims are within the skill of one of ordinary skill in the art and it would have been obvious to optimize the dose schedules and dose levels to determine optimal schedules and dosages.

Conclusion

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
January 27, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600